



**TLV**

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TANDVÅRDS- OCH

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LÄKEMEDELSFÖRMÅNSVERKET

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## **Quality and economy must not be contradictory**

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### **The Swedish experience of assessing the cost and effect of drugs**

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**Health Economist**

**Dental and Pharmaceutical Benefits Agency**

# The Dental and Pharmaceutical Benefits Agency (TLV)

- Our goal is to get the maximum amount of health out of the taxpayers money spent on pharmaceuticals and dental care
- Independent government agency
- Established in 2002

# Remit of the agency in the pharmaceutical area

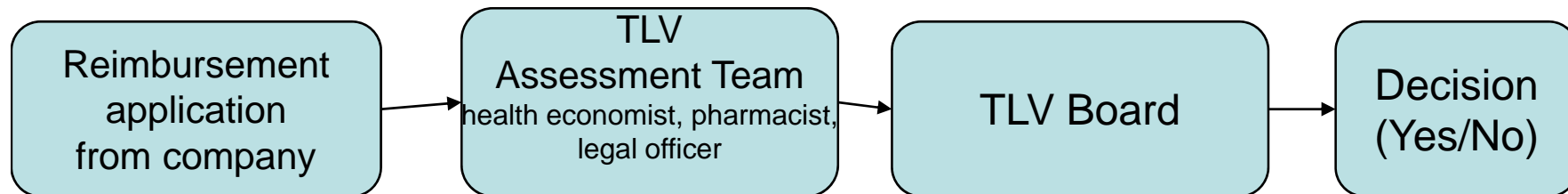
- Pricing and reimbursement decisions for all prescription pharmaceuticals
- Reimbursement review of older products.  
To assess if the existing range of products are cost-effective

*” Prescription drugs shall be included on the Pharmaceutical Benefits Scheme and the price for the drug shall be set provided:*

1. *that the costs of using the drug ...appear reasonable from the medical, humanitarian and economic aspects,”*

(Act on Pharmaceutical Benefits 2002)

# Reimbursement decision process



Price  
Effect documentation  
Health economics

Evaluation  
Contact w/company  
- questions  
- additional analyses

Prepare a memo to the board with proposal for decision

11 members  
- medicine  
- health economics  
- users

Deliberation w/company

Max 180 days  
Average 91

# Evaluating quality and costs

- The applicant (i.e the manufacturer) must prove that the product is effective and cost-effective.
- At the point of a reimbursement decision the data available is often limited to the registration trials.
- This means that long-term effects and cost-effectiveness will have to be modelled.
- There is often a need for more evidence to be developed over time.

# Cost-effectiveness is evaluated from a societal perspective

- Many pharmaceuticals may have an impact on both costs and effects that fall outside of the healthcare system.
- These costs can quite often be substantial and often much larger than the actual drug or healthcare cost.
- For example: In depression drug costs account for less than 5 percent of total societal cost of the disease.
- The societal perspective is important because important benefits often appear in sectors outside the healthcare system.

# Decision making criteria

## **Human value**

- respect for equality

## **Need and solidarity**

- those in greatest need take precedence

## **Cost-effectiveness**

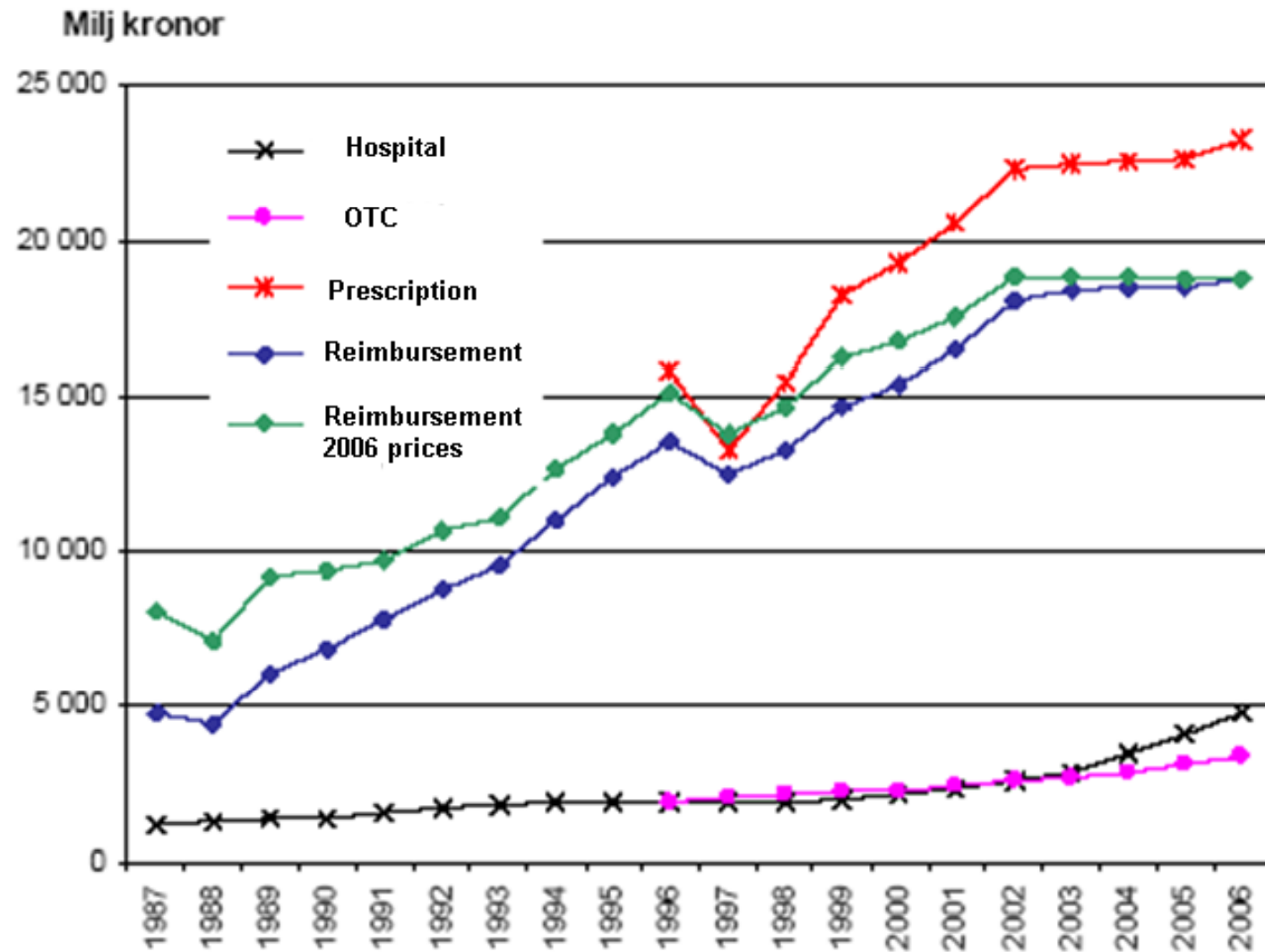
- from a societal perspective

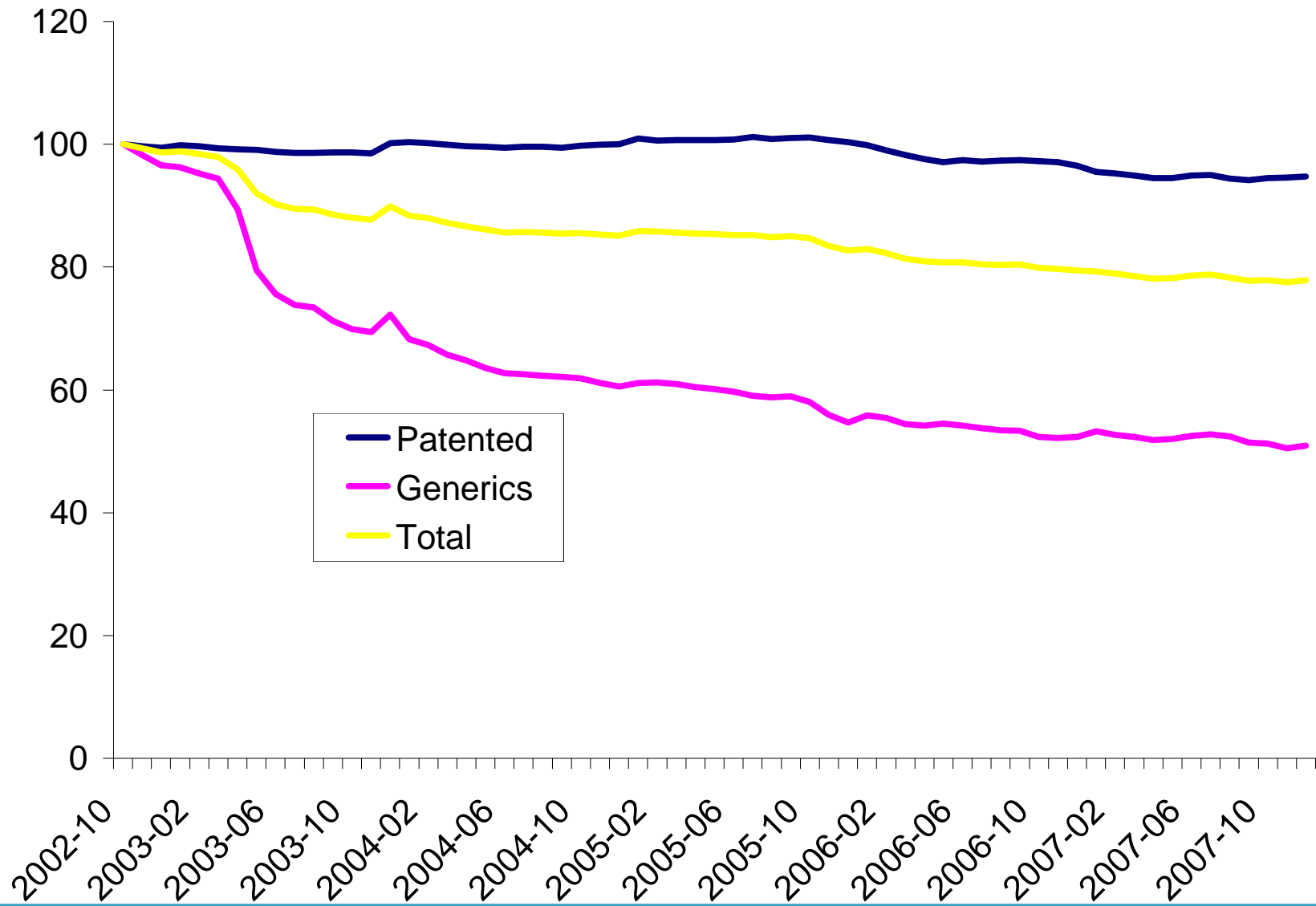
# Cost-containment vs Cost-effectiveness?

- Cost-containment and budgetary restrictions are not reimbursement criteria.
- If society values health it should be willing to devote more resources to health care if new effective methods are introduced.
- Keeping costs from rising too much is however a concern for the budget holders.
- In Sweden an effective system for generic substitution has kept cost growth limited despite an increasing use of new innovative drugs.



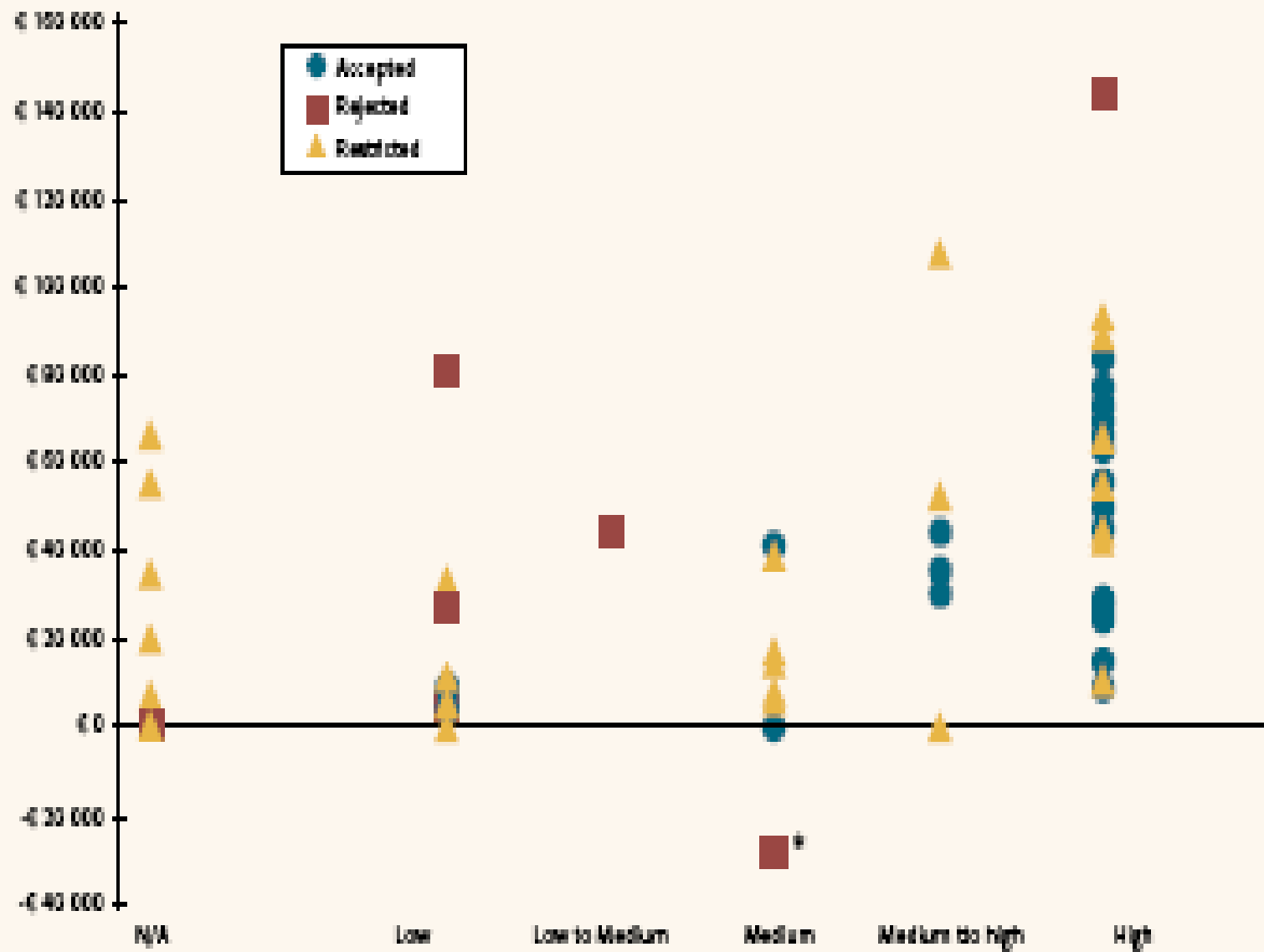
# Drug expenditure





# Weighing cost-effectiveness against need and solidarity

- In the decisionmaking the law states that we have to balance cost-effectiveness against other criteria.
- Mainly this is done against the principle of need and solidarity.
- We should be willing to pay more for drugs used against severe conditions.
- A drug which is more effective than current treatment options can have a higher price. Increases in quality have a value.



\* Lower effect and lower cost than the comparator. Thus a saving per QALY lost.

# Summary

- Balancing cost-effectiveness against need (disease severity)
- Effective generic substitution can contribute to cost-containment but ...
- Health has an intrinsic value and society should be willing to pay for gains in health.
- Health economic evaluations help guide decisions on reimbursement and setting of priorities.